DEC 17 2004

BioCheck, Inc.

CARDIAC- 1 RAPID TEST

FOR THE QUALITATIVE DETERMINATION OF CARDIAC TROPONIN I In Human Whole Blood, Plasma or Serum

Catalog No.: 850116

I. MANUFACTURER:

BioCheck, Inc.
323 Vintage Park Drive
Foster City, CA 94404
Phone: (650) 573-1968
Fax: (650) 573-1969
Regulatory Contact: Hellen Professional Services
Phone: (818) 709-5646

II. DEVICE NAME and CLASSIFICATION:

Proprietary Name:	*BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test*
Catalog Number:	850116
Common Name:	BioCheck *Cardiac-1 Rapid Test*
Classification Name:	Creatine Phosphokinase/Creatine Kinase or Isoenzymes Test System (862.1215)

III. INTENDED USE and ASSAY PRINCIPLE:

The *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test* is intended for the qualitative determination of cardiac troponin I in human whole blood, plasma or serum. Measurement of troponin I values are useful in the evaluation of acute myocardial infarction (AMI).

The *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test* is a colloidal gold/antibody conjugate-based immunoassay designed for the detection of cTnI in human whole blood, plasma and serum samples. To perform the *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test*, the sample is dispensed into the sample well. The red cells in the whole blood will react with certain biochemical reagents (such as anti-red blood cells) which are immobilized in the sample pad. This reaction will cause the red blood cells to bind to the sample pad, allowing only the plasma to travel forward. CTnI that is present in the specimen is bound by a gold-antibody conjugate forming a gold-antibody-antigen complex. This complex migrates across the membrane by capillary action and reacts with three anti-cTnI monoclonal antibodies immobilized in the test region to produce a pink color band when the cTnI concentration is equal to or greater than 1.5 ng/ml. If cTnI is not present in the specimen, there is no line in the test line area. The mixture continues to migrate to the procedural control line area and produce a pink color band. If no procedural control line is present, the sample is invalid and should be retested.

IV. SUBSTANTIAL EQUIVALENCE:

The *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test* is a modification of the existing BioCheck Serum Troponin I Rapid Test (formerly, the VBL Serum Troponin I Test, K023505; currently manufactured by BioCheck, Inc., Foster City, CA 94404). The original rapid troponin I test was cleared for use on serum samples, and the new, reformulated device can be used to detect human cTnI in **whole blood, plasma or serum** specimens. The intended use of the product has not been altered significantly, only expanded to include the use of whole blood and plasma samples.

V. TEST PERFORMANCE:

1. *Precision*

- PRECISION--BETWEEN RUNS AT FOUR DIFFERENT TESTING SITES – SERUM Samples
  Four laboratories were provided with blind **serum** samples that had been spiked with purified complex cTnI *. Three serum samples containing 0, 1.5, and 3.0 ng/ml cTnI were prepared. Five blind replicates of each sample were tested in each site for a total of 15 tests per site. All samples were also tested in manufacture's laboratory. The assay results demonstrated 100% agreement in between run proficiency and 100% agreement between sites using serum samples.

- PRECISION--BETWEEN RUNS AT FOUR DIFFERENT TESTING SITES – WHOLE BLOOD Samples
  Between run precision was evaluated at four different sites. Four laboratories were provided with blind **whole blood** samples which were spiked with purified complex cTnI. Samples were prepared containing 0 ng, 1.5 ng and 3.0 ng/ml of cTnI. Five blind replicates of each sample were tested at each site for a total of 15 tests per site. All samples were also tested in the manufacturer's laboratory. The assay results demonstrate 100% agreement in between-run proficiency, and 100% agreement between sites using whole blood samples.

2. *Recovery Study*

Sample recovery was tested using serum samples and whole blood samples with the *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test.*

For the serum evaluation, normal human serum was supplemented with partially purified human cTnI complex to yield cTnI concentrations of 0, 0.5, 1.0, 1.5 and 3.0 ng/ml. The whole blood samples were tested by using normal human whole blood specimens spiked with partially purified human cTnI complex to yield cTnI concentrations of 0, 0.5, 1.0, 1.5 and 3.0 ng/ml.

The spiked samples were tested in six replicates using the *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test.* The data showed 100% agreements between the expected and the observed results at each cTnI concentration for both serum and whole blood samples (results shown as # positive results/total # tested).

V. TEST PERFORMANCE:

3. *Interference*

The following potentially interfering substances do not appear to interfere with the determination of cTnI in the *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test* up to the levels indicated below. Identical results were observed in the serum-only test.

Analyte	Test Level	Analyte	Test Level
Biotin	200 ng/ml	Human muscle Troponin T	2.5 µg/ml
Bilirubin	20 mg/dl	Human muscle Troponin I	2.5 µg/ml
Hemoglobin	1200 mg/dl	Cholesterol	800 mg/dl
Rabbit skeletal muscle Troponin C	2.5 µg/ml	Triglyceride	1250 mg/dl
Human cardiac Troponin T	2.5 µg/ml		

In vitro testing of the following common-used drugs revealed no interference at the upper level of the therapeutic range in the *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test.* Identical results were observed in the serum-only test.

Analyte	Test Level	Analyte	Test Level
Acetaminophen	30 µg/ml	Digitonin	10 µg/ml
Acetylsalicylic acid	200 µg/ml	Digoxin	10 µg/ml
Adenine	10 µg/ml	Dopamine	10 µg/ml
Albumin (bovine)	50 mg/ml	Erythromycin	20 µg/ml
Allopurinol	20 µg/ml	Gentistic acid	10 µg/ml
Ambroxol	10 µg/ml	Isoproterenol	10 µg/ml
Ampicillin	20 µg/ml	Isosorbide dinitrate	50 µg/ml
Ascorbic acid	20 µg/ml	Nifedipine	200 µg/ml
Atenolol	10 µg/ml	Nystatin	10 µg/ml
Atropine	10 µg/ml	Oxazepam	10 µg/ml
Caffeine	20 µg/ml	Oxytetracycline	10 µg/ml
Captopril	10 µg/ml	Propranolol	10 µg/ml
Chloramphenicol	25 µg/ml	Theophylline	20 µg/ml
Cinnarizine	10 µg/ml	L-thyroxine	10 µg/ml
Cyclophosphamide	125 µg/ml	Urea	400 µg/ml
Cyclosporine	10 µg/ml	Uric acid	100 µg/ml

4. ***Clinical Comparison***

- CLINICAL CORRELATION STUDY
  A total of 245 patient serum samples were tested using the *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test.* Results were compared with a commercially available quantitative ELISA assay for cTnI as shown below:

BioCheck Whole Blood / Plasma / Serum cTnI Rapid Test	***BioCheck, Inc. Troponin I ELISA Test***	
	≥ 1.5 ng/ml	**< 1.5 ng/ml**
+	73	5
–	2	165
Total	75	170

Sensitivity = 73 / 75 = 97.3%
Specificity = 165 /170 = 97.1%
Overall Accuracy = 238 /245 = 97.1%

- CORRELATION STUDY between WHOLE BLOOD and PLASMA Samples
  Sixty-eight (68) patient whole blood samples were collected and plasma isolated. The paired samples were tested using the *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test.* The agreement between the whole blood test and plasma test was 100% (68/68).

V. TEST PERFORMANCE:

- CLINICAL STUDIES – CONFIRMED MI Patients: *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test* and BioCheck ELISA Test
  Twenty-four (24) whole blood specimens from confirmed MI patients were tested with the *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test* and BioCheck cTnI ELISA Test. Among these specimens, 23 were found to have positive test results and the agreement with the patient status was found to be 95.8% (23/24).

- CLINICAL STUDIES – NON-MI Patients: *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test* and BioCheck ELISA Test
  Similarly, whole blood specimens from non-MI patients (n=44) were tested with the *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test* and the BioCheck cTnI ELISA Test. Negative results were obtained for both test protocols for all 44 specimens and 100% (44/44) agreement was achieved.

- CORRELATION of ASSAY RESULTS BETWEEN WHOLE BLOOD AND SERUM SAMPLES
  A pair of samples, one whole blood (WB) and one serum (S), were collected from each of 20 individuals. The whole blood and serum samples from each individual were spiked with the same amount of purified complex cTnI. The samples of 17 individuals were prepared containing ≥ 1.5 ng/ml of cTnI while samples of 3 individuals containing < 1.5 ng/ml of cTnI. The agreement between the use of whole blood and serum was 100%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 2004

Biocheck, Inc.
c/o Robin J. Hellen, M.S.
Hellen Professional Services
9418 Lasaine Avenue
Northridge, CA 91325

Re: k041619
Trade/Device Name: BioCheck, Inc. Whole Blood/ Plasma/ Serum cTnl Rapid Test
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/ creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: November 8, 2004
Received: November 17, 2004

Dear Ms. Hellen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: *BioCheck, Inc.*
Whole Blood/Plasma/Serum cTnI Rapid Test

Indications for Use:

The *BioCheck Whole Blood/Plasma/Serum cTnI Rapid Test* is intended for the qualitative determination of cardiac troponin I in human whole blood, plasma or serum. Measurement of troponin I values are useful in the evaluation of acute myocardial infarction (AMI).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041619